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IN THE SUPREME COURT OF THE UNITED STATES

October Term, 1974
No. 74-1367

MAURICE W. ROSENBERG, M.D.,

Petitioner,

vs.

UNITED STATES OF AMERICA,

Respondent.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

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TO THE UNITED STATES SUPREME COURT, OCTOBER TERM, 1974:

The Petitioner, MAURICE W. ROSENBERG, M.D. prays that a writ of certiorari issue to review the judgment and opinion of the United States Court of Appeals for the Ninth Circuit filed March 31, 1975. In the case the Ninth Circuit Court of Appeals, Judge Ely dissenting, issued an opinion in direct conflict with the United States Court of Appeals for the District of Columbia

opinion in United States v. Moore, 505 F.2d 426 (1974) (cert. granted 2/18/75, No. 74-759). It is therefore respectfully submitted that the petition for writ of certiorari be granted so that these matters may be presented at the same time for a hearing on their common issuesof fact and conflicting decisions relating thereto. This was the practice adopted by this Honorable Court when two conflicting Court of Appeal's decisions are issued virtually simultaneously. Immigration and Naturalization Service v. Errico, 385 U.S. 214, 87 S.Ct. 473 (1966). See also Rules of the Supreme Court of the United States, Rule 19(b).

The resolution of these issues in conflicting decisions is of major importance to the medical profession in the United States.

One of the major purposes of the Controlled Substances Act of 1970 was to alleviate problems under the old Harrison Act faced by physicians who treated patients for narcotic addiction. The interpretation of the new Act adopted by the majority in this case would pose exactly the same threat to physicians in private practice. An immediate resolution of the conflict in Circuits concerning the interpretation of this statute is therefore an urgent necessity.

OPINION BELOW

The opinion of the Court of Appeals, not yet reported, appears in the Appendix hereto as Appendix "A". No opinion was rendered by the United States District Court for the Central District of California.

JURISDICTION

The judgment of the Court of Appeals for the Ninth Circuit was entered on March 31, 1975, affirming the Petitioner's conviction on 27 counts of violating Title 21, U.S.C. §841(a)(1). A copy of the judgment, in letter form, obtained from the Office of the Clerk, United States Court of Appeals for the Ninth Circuit appears in the Appendix as Appendix "B". The Court's jurisdiction is invoked pursuant to Title 28, U.S.C. §1254(1) and Rule 22(2).

QUESTIONS PRESENTED

1. Whether the general criminal penalties of Title 21 U.S.C. §841 apply to physicians registered pursuant to 21 U.S.C. §822 who are acting within the scope of the registration pursuant to §822?

2. Assuming arguendo that 21 U.S.C. §841 applies to a §822 registrant, whether a

medical doctor registered pursuant to §822 may only be convicted of illegal "dispensing" as opposed to illegal "distributing"?

3. Whether the language contained in Title 21 U.S.C. §802(20) and in particular the phrase "in the course of professional practice or research" contained therein, are vague, ambiguous, and void, and therefore incapable of sustaining a criminal prosecution?

4. Whether the regulation promulgated by the Attorney General and contained in 21 C.F.R. §1306.04(a) which provides that a prescription for a controlled substance must be issued "for a legitimate medical purpose" and "in the usual course of his professional practice," and which limits the scope of the exception to criminal prosecution contained in §841 violates the doctrine of separation of powers and deprived the petitioner of his Sixth Amendment right to jury trial and due process of law.

STATUTES INVOLVED

Selected relevant portions of the Controlled Substances Act of 1970, Title 21, United States Code, §§801, et seq., are attached hereto as Appendix "C".

STATEMENT OF THE CASE

The petitioner was charged in a 27-count indictment in the United States District Court for the Central District of California. Twelve counts charged the doctor with unlawful distributing of dextro amphetamine, a Schedule II controlled substance; nine counts charged the doctor with unlawfully distributing secobarbital, a Schedule III controlled substance; and six counts charged the doctor with unlawfully distributing meprobamate, a Schedule IV controlled substance. Following trial by jury, a judgment of conviction on each of the 27 counts was entered in April 15, 1974, the Honorable William P. Gray, Judge Presiding.

A timely appeal was taken to the United States Court of Appeals for the Ninth Circuit, which court, on March 31, 1975, entered its judgment affirming the conviction on each count, Judge Ely, dissenting.

The facts produced before the District Court indicated that Dr. Rosenberg was licensed as a physician by the State of California and registered pursuant to Title 21 U.S.C. §§821, 822 and 823. Undercover narcotics agents made appointments with Dr. Rosenberg and, at arrival at his office, the doctor's nurse recorded their name and address and collected a fee for the office visit. The initial visit required a $15.00 fee, while subsequent visits were charged at the rate of $8.00. In a typical case, the agents would ask for a

controlled substance and the petitioner would inquire as to the agent's need for the particular drug. The petitioner would then issue a prescription for a quantity of the drug. The drugs for which the prescriptions were issued were, in each case, controlled substances in Schedules II, III or IV, and thus within the scope of petitioner's federal registration and state license.

REASONS FOR GRANTING A WRIT

---

1. The decision and judgment of the Court of Appeals for the Ninth Circuit in the instant matter is in direct conflict with the opinion of the United States Court of Appeals for the District of Columbia in the case United States v. Moore, 505 F.2d 426 (1974) (cert. granted, Feb. 18, 1975, #74-759). In Moore it was determined that the provisions of Title 21 U.S.C. §841 are inapplicable to a physician who has prescribed medication within the ambit of his registration pursuant to 21 U.S.C. §822. The petitioner here, a physician licensed within the State of California and registered pursuant to the federal act, was convicted for prescribing medication listed as controlled substances under 21 U.S.C. §812, Schedules III, IV and V. The registration of the petitioner permits the prescribing of each of these drugs. An analysis of the statutory provisions contained in Title 2 of the Drug Abuse Prevention and Control Act of 1970, hereafter

referred to as "The Act" indicates that a physician registered pursuant to that Act may not be prosecuted under §841 with regard to controlled substances which come within the ambit of the physician's registration.

As indicated in the dissent of Judge Ely below, Part C of the Act, contained in 21 U.S.C. §§821-829, is a "closed" system of drug distribution of "legitimate handlers." H.R. Rep. 1444, 91st Congress, 2d Sess. 6 (1970) (1970 U.S.C. Cong. and Admin. News 4571-72). Pursuant to §822(a) physicians and other professionals are required to register annually with the Attorney General. As with the petitioner, if a physician is licensed by the state, the Attorney General grants registration pro forma. The limitation upon such registration is that a physician may not deal in controlled substances which have no medical value, such as those contained in Schedule I.

The "closed system" of the Act provides for a series of penalities both criminal and administrative in nature. Section 824 provides for denial, revocation, or suspension of registration. Also, in Part D, §§842 and 843 provide criminal penalties with regard to "registrants" and persons who are "subject to the requirements of Part C (the registration requirements)." Thus, the penalty provisions of §§842 and 843 directly relate to registrants under the Act. In contrast, the general criminal penalties of §841 apply to all persons "except as authorized by this subchapter." The "except as authorized" provisions of §841 directly parallel

the language of §822 with regard to registration and which states that "persons registered . . . are authorized to possess, manufacture, distribute, or dispense such substances . . . to the extent authorized by their registration. . . ."

The penalty provisions of §§842 and 843, while materially lower than the penalty provisions under §841, are substantial. Thus, the Act, with regard to the closed system, provides for policing and imposition of penalties for violations of that system.

The diminished penalty is itself consistent with the purposes of the Act with special regard to physicians and researchers. The precursor to the Act was the Harrison Act. Criminal prosecutions of physicians under the Harrison Act for treatment of narcotics addicts created great uncertainty in the medical profession with regard to permissible scope of such treatment. The Act, on the contrary, reflects a desire to segregate those possible penalties for physicians or registrants from the general criminal sanctions. Thus, the Judiciary Committee's report of the Senate Bill states that §501 of that bill (similar to §841) dealt with "drug traffickers." S. Rep. 91-613, 91st Cong., 1st Sess. 8 (1969). Sections 502 and 503 (similar to §§842 and 843) contained "penalties . . . for those involved in the legitimate drug trade." Ibid. at page 9. As indicated in the opinion in United States v. Moore, supra, at pages 432-433, the Senate report and Senate debate clearly indicated that the general penalty provisions were directed at

drug traffickers while the specific provisions of §§842 and 843 dealt with registrants acting within the scope of their registration. In this way, Congress attempted to alleviate the difficulty under the Harrison Act which resulted from a physician's unwillingness to accept addicts as patients for fear of criminal liability.

The registration penalties thus insure that the protections of the Act will not be thwarted by imposing penalties for violation of various registration provisions. Similarly, loss or suspension of registration is possible and comes automatically through loss of state license.

However, it is clear that a physician who deals in controlled substances outside the scope of his registration is subject to the penalties of §841. Thus, a physician who deals in drugs with no medical purpose as contained in Schedule I (including heroin) is not "authorized" under §822 to dispense or distribute these drugs, and thus does not fall within the "except as authorized" exception of §841. The upshot of the foregoing is that the language "in the course of professional practice or research" contained in the defintion of "practitioner" in §802(20) is not and cannot be a limitation upon the practitioner exception contained in §841. Aside from the statutory and legislative intent, there are several cogent reasons for this result.

First, and most simply, the "in the course of professional practice or research" language is not contained in the penalty provisions, but merely within the practitioner definition. Secondly, a clear grammatical analysis of that phrase indicates that it modifies the scope of

the license or registration and not the scope of the registration exception. Subsection 20 of §802 therefore limits the practitioner exception to those persons whose professional practice or research enables them to become licensed by the United States or the jurisdiction within which he practices to distribute or dispense the controlled substance. Thus, and in view of the rule that penal statutes must be construed in favor of the accused, it appears that the "in the course of professional practice or research" language is not meant as a restriction upon the "except as authorized" exception of §841. Smith v. United States, 360 U.S. 1 (1959).

Furthermore, the position taken by the majority below with regard to that language results in numerous inconsistencies and absurdities in the statutory scheme. For example, §841 prohibits an unauthorized person to "manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance. . . ."

Under the Court's view of the "in the course of professional practice or research" language, it would be impossible for any person to illegally "dispense" a controlled substance.

For, under the Court's view, a registrant who is acting in bad faith is not acting "within the course of professional practice or research." He thus loses the protection of the §841 exception, since he can no longer be termed a "practitioner." Section 802(10) nonetheless defines the term "dispense" as "to deliver a controlled substance

to an ultimate user or research subject by, or pursuant to the unlawful order of, a practitioner . . . the term 'dispenser' means a practitioner who so delivers a controlled substance to an ultimate user or research subject." Thus, there can not be a "dispensing" without an action of a "practitioner." For, a "dispensing" only arises through delivery of the controlled substance either by a practitioner or pursuant to the order of a practitioner. Thus, if the majority below is correct, and the "in the course of professional practice" language restricts the definition of practitioner, a registrant not acting "in the course of professional practice" is not a practitioner and therefore cannot "dispense" a controlled substance. Similarly, a person acting upon such person's order, would not be "dispensing" a controlled substance. Thus, there could not be, under the majority's view, an illegal "dispensing." However, it is clear that §841 prohibits an illegal "dispensing." The solution to this dilemma is that the practitioner exception is not limited by the "in the course of professional practice" language. Thus, a practitioner physician who delivers a Schedule I controlled substance would be, under §802(10) "dispensing" that controlled substance. However, such delivery would be outside the scope of the physician's registration and, thus, such "dispensing" would be illegal.

A further difficulty results under the majority's analysis in view of the fact that a pharmacy may only "dispense" a controlled substance pursuant to the prescription of a

"practitioner" and "registrant." 21 U.S.C. §829. Violation of that section may be punished pursuant to §842(a)(1). Section 842(c)(1) provides for a civil penalty of not more than $25,000 unless the act is done knowingly. Thus, a pharmacy which delivers a controlled substance pursuant to a prescription may be subject to the penalty with no scienter requirement. Under the majority's view, a physician loses his standing as a "practitioner" if not acting within the "course of professional practice." Thus, a prescription written by such person would not be a proper prescription under §829 and a pharmacy that fills the prescription and delivers the controlled substance would be subject to the $24,000 fine under §842(c). Such an irrational result clearly cannot be presumed to have been the intent of Congress. Rather, the practitioner exception is obviously meant to apply to a physician who prescribes a drug within the scope of his registration, i.e., a drug for a medical purpose. In such a case, his prescription, although in what the majority might term "bad faith" falls within the definition of §829 and the pharmacy is thus shielded from the imposition of civil penalties.

The result is that, should a physician act in a manner which is not determined to be legitimate medical practice, appropriate relief may be sought through revocation of his state license or revocation of his registration. In this way, a determination of the proper scope of medical treatment is made by medical peers and not by a jury at its whim. Linder v. United States, 268 U.S. 5, 18 (1925). This

serves to reinforce the purposes of the Act which was to remove the threat of unwarranted prosecution and loss of license from physicians who treated narcotics addicts under the Harrison Act.

It thus appears that the legislative history and purposes of the Act, the changes made from the Harrison Act, the penalty scheme and closed system established, and a statutory analysis of the various terms within the Act all clearly indicate that a physician registered under the Act may not be prosecuted pursuant to §841 so long as he delivers controlled substances which he is permitted to deliver under his federal registration. Inasmuch as the petitioner here dealt solely in Schedules III, IV and V substances, which fall within his registration, he could not have been convicted pursuant to §841. The importance of this issue to the medical profession mandates a resoltuion of this question by this Honorable Court.

2. While there is a diversity of view among the circuits as to the propriety of charging a physician pursuant to §841 if he is delivering substances within the scope of his registration, there is also a split in the circuits with regard to the ability to prosecute a physician under any circumstances of unlawful "distribution" as opposed to unlawful "dispensing." In United States v. Leigh, 487 F.2d 206 (1973), the Fifth Circuit determined that a doctor may be indicted, tried and convicted for unlawful dispensing of a controlled substance but not with unlawful distribution. The analysis made by the Court

is based upon a statutory construction of §802(10) which defines the word "dispensing." That section states in part:

> "The term 'dispense' means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner . . . The term 'dispenser' means a practitioner who so delivers a controlled substance to an ultimate user or research subject."

In contrast, §802(11) defines "distribute" as:

> "The term 'distribute' means to deliver (<u>other than by administering or dispensing</u>) a controlled substance. The term 'distributor' means a person who so delivers a controlled substance."

Finally, the term "administer" as defined in §802(2) requires the direct action of a "practitioner" as a portion of the definition. Therefore the notion of "distribution" is mutually exclusive with activities of a practitioner or physician, who, <u>by definition</u>, may only "administer" or "dispense" a controlled substance.

The Ninth Circuit in the instant matter, at slip opinion, page 15, rejects the argument made in <u>Leigh</u> relying upon <u>United States v.</u>

Black, No. 73-3003 (9th Cir. 3/11/75), and United States v. Badia, 490 F.2d 296 (1st Cir. 1973). In United States v. Badia, supra, the First Circuit stated at 490 F.2d at 298 in footnote 4:

> "We think the reason Congress included the term 'dispense' in §841(a)(1) was to compel physicians to become properly licensed."

The analysis made by the First Circuit of the purpose of the "dispensing" language overlooks the fact that a "dispensing" can only be made pursuant to the lawful order of a practitioner. The definition of practitioner, as stated in §802(20) requires that he be licensed either by the United States or the jurisdiction in which he practices. Thus, if a "physician" is not licensed, he is not a practitioner and any order made by him will not come within the definition of "dispense" under §802(10). Moreover, the view of the First Circuit suffers from the same difficulties discussed above with regard to the necessary conclusion under that view that no person can be convicted of unlawful "dispensing."

Furthermore, it is important to recognize that the exception provided in 21 U.S.C. §829 joins the term "dispensed" with "practitioner," thus contemplating the utilization of a prescription by any practitioner as a proper "dispensing." At most, therefore, even if §841 can be applied to a practitioner with regard to substances covered by his registration, it is submitted that

the improper utilization of the prescription would subject the physician to prosecution for unlawful dispensing.

Petitioner in the present case was charged only with distribution. No allegations of "dispensing" were made. As stated by the Court in United States v. Leigh, supra, 487 F.2d at 208:

> "[O]ne may not be charged with one crime and convicted of another. The Schooner Hoppet and Cargo v. United States, 7 Cranch 389, 11 U.S. 389, 3 L.Ed. 380."

There are thus three prevalent views manifested with regard to the application of the Act to practitioners and physicians. The Ninth Circuit, as indicated in the opinion of the Court below, has held that a physician may be prosecuted for unlawful distribution pursuant to §841. The Fifth Circuit, in United States v. Leigh, supra, had held that a physician may be prosecuted for unlawful dispensing, but not distribution, pursuant to §841. And the District of Columbia Circuit, in United States v. Moore, supra, and Judge Ely in his dissent below, argue that a practitioner may only be prosecuted pursuant to §§842 and 843. This divergence of opinion should be resolved by this Honorable Court, and the instant case presents a factual background against which a discussion of each of these issues is appropriate.

3. The position adopted by the Ninth Circuit in the opinion below relies upon language included in the definition of practitioner in 21 U.S.C. §802(20) to limit the extent of the practitioner exception under §841. It thus becomes necessary to determine whether the Act is clear in its intent to apply such language as an exception, and, if so, whether that language "in the course of professional practice or research" is constitutionally vague, ambiguous and void.

Initially, it should be noted, as has been stated above, that there is a conflict among the Circuits as to whether the language "in the course of professional practice or research" contained in §802(20) is meant as a limitation upon the practitioner exception under 21 U.S.C. §841. It is submitted that when the language is viewed in the appropriate context of the Act, and in view of the legislative history and the location of the language in the definition portion of the Act as opposed to the penalty provision of the Act it is apparent that the language was intended to modify the scope of the "license" which gave rise to the ability to obtain federal registration.

Even assuming, however, that the phrase "in the course of professional practice" is utilized to modify and limit the extent of the "practitioner" exception, the language chosen by the Legislature is too vague and ambiguous to satisfy the constitutional requirements of due process of law.

> "'The constitutional requirement of definiteness is violated by a criminal statute that fails to give a person of ordinary intelligence fair notice that his contemplated conduct is forbidden by the statute.'" Bouie v. City of Columbia, 378 U.S. 347, 351-352, 84 S.Ct. 1697, 1701 (1964).

Referring to the case of Connally v. General Construction Co., 269 U.S. 385, 391, 46 S.Ct. 126, 127, this Court in Bouie v. City of Columbia, supra, at 378 U.S. 351, 84 S.Ct. 1701, held that due process was violated where the statute was not "sufficiently explicit to inform those who were subject to it what conduct on their part will render them liable to its penalties."

As indicated in the dissenting opinion of Judge Ely, below, at slip opinion page 22, the majority opinion finds it necessary to rely upon the Harrison Narcotics Law in order to substantiate its conclusion that the phrase is not vague. As further discussed by Judge Ely, the distinction between the Harrison Act and the new Act was based in large measure upon an attempt to limit the criminal liability of a physician who undertook medical treatment of an addict. The new Act differed in substantial respects from the applicable and similar provision of the Harrison Act which read:

> "Nothing contained in this section shall apply --

"(a) to the dispensing of any of the aforesaid drugs to a patient by a physician . . . registered under this Act in the course of his professional practice only."

Thus the crucial element of dispensing "to a patient" . . . "only" have been eliminated from the present Act.

The majority below further relied upon an administrative regulation of the Attorney General contained at 21 C.F.R. §1306.04(a). That regulation, which was relayed to the jury during the course of the instructions, required that a prescription, to be valid as an exception to criminal prosecution, must be for a "legitimate medical purpose." Aside from the separation of powers difficulties discussed below, it is entirely inappropriate to rely upon such an administrative regulation in order to resolve the issue of ambiguity in the underlying statute. In fact, the very existence of the regulation lends credence to the petitioner's position in that it is a tacit admission on the part of the Executive Branch that the phraseology contained in the Act itself is insufficient to specify the nature of the prohibited conduct. The reliance upon the regulation by the majority below further serves to highlight the ambiguity and vagueness inherent in the language of the Act. For, it is apparent that "in the course of professional practice" is neither similar nor equal to "for a legitimate medical purpose." Each of the prescriptions under consideration here was clearly issued during the course of

the petitioner's medical practice. He was licensed as a physician by the State of California; he was registered to dispense the substances by the federal Government; and he issued the appropriate and proper prescription for their delivery to the patient. The words are therefore void on their face and thus not susceptible of sustaining a criminal prosecution. Strict construction in favor of the accused is required and further serves to highlight the incorrectness of the majority opinion. Smith v. United States, supra.

4. The indictment against the petitioner charged that he had distributed the controlled substances not "in the usual course of professional practice" and not "for any legitimate medical research purposes." The latter phrase was obtained directly from the Attorney General regulation referred to above. 21 C.F.R. §1306.04(a). Slip Opinion, page 10. The trial court included references in the course of jury instructions to "good faith for legitimate medical treatment in the usual course of his professional practice." Slip Opinion, page 11. The superimposition of this criterion of "legitimate medical purpose" upon the practitioner exception violates the separation of powers doctrine which is expressed in the first three articles of the United States Constitution. This Court has considered in a variety of circumstances the unconstitutionality of executive action as it affected judicial determination. In L. P. Stewart & Bros. v. Bowles, 322 U.S. 398, 404, 64 S.Ct. 1097, 1110 (1944), this Court specifically noted that "it is for Congress to prescribe the

penalties for the laws which it writes. It would transcend both the judicial and the administrative function to make additions to those which Congress has placed behind the statute." In Toussie v. United States, 397 U.S. 112, 90 S.Ct. 858 (1970), this Court considered a Selective Service regulation which extended the statute of limitations for failure to register for the draft by making the necessity to register a continuing obligation. It was determined that such action was legislative and therefore could not be imposed through executive or administrative action.

In Reid v. Covert, 354 U.S. 1, 38-39, 77 S.Ct. 1222, 1242 (1957), the issue arose as to the ability of the President, as Commander-in-Chief of the Armed Forces to make changes in the substantive and procedural military law. This Court prohibited such action, finding that "such blending of functions in one branch of the Government is the objectionable thing which the draftsmen of the Constitution endeavored to prevent by providing for the separation of governmental powers."

Thus, it is not only inappropriate to rely upon the Attorney General regulation to interpret the meaning of the words of statute, but the possibility of a jury verdict based in part upon criteria imposed by such regulation violates the doctrine of separation of powers and denied the petitioner due process of law.

CONCLUSION

This petition presents fundamental issues regarding the applicability of the Controlled Substance Act to medical doctors. Various Courts of Appeal have come to completely contrary conclusions with regard to the applicability of Title 21 U.S.C. §841 to physicians.

However, the legislative history of the Act indicates a desire on the part of Congress to shield the medical profession from prosecution lodged against physicians who are willing to treat narcotics addiction. Changes made between the Controlled Substances Act and the former Harrison Act evidence and buttress this intention. The interpretation of the Act as made by the majority below, results in inconsistencies and illogical results under the Act. Certain language is thereby rendered superfluous, and illogical application of the Act results.

The analysis made by petitioner, on the contrary, is consistent with historical constitutional and statutory analysis, fulfills the legislative purpose, and renders the Act rational.

In either event, the effect upon the medical profession with regard to liability for criminal prosecution under the Act is one of utmost importance to both the nation and the administration of justice. The issues presented are supplementary and complementary to those in United States v. Moore, 505 F.2d 426 (1974)

cert. granted 2/18/75, No. 74-754 and it is respectfully requested that this petition for writ of certiorari be granted and that this case be set for oral argument together with United States v. Moore, supra.

Respectfully submitted,

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APPENDIX A

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA, *Plaintiff-Appellee,* vs. MAURICE W. ROSENBERG, M.D., *Defendant-Appellant.*	No. 74-2197 OPINION

[March 31, 1975]

Appeal from the United States District Court for the Central District of California

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Before: LUMBARD,* ELY, and WRIGHT, Circuit Judges.

LUMBARD, Circuit Judge:

Dr. Maurice W. Rosenberg appeals from a judgment of conviction entered on April 15, 1974, in the Central District of California, following a jury trial at which he was found guilty of 27 counts of distributing a controlled substance in violation of 21 U.S.C. § 841(a)(1).[1] Dr. Rosenberg was sentenced to concurrent terms of two years in prison for each violation and was fined $20,000. Imposition of the prison sentences was suspended and payment of the fine was stayed pending appeal. Dr. Rosenberg argues that the statute under which he was convicted is unconstitutional, that there was insufficient evidence to convict him of

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*United States Court of Appeals for the Second Circuit, sitting by designation.

[1]Twelve of the counts charged the doctor with unlawfully distributing dextroamphetamine (dexedrine), a schedule II controlled substance; nine of the counts charged him with unlawfully distributing secobarbital (seconal), a schedule III controlled substance; and six of the counts charged him with unlawfully distributing meprobamate (miltown), a schedule IV controlled substance. See 21 U.S.C. § 812.

violating that statute, and that his right against self incrimination was violated. We affirm.

Rosenberg was a seventy-five year old doctor who had been practicing medicine in California for approximately 30 years. During 1973 the doctor was visited by five undercover agents working for the California Bureau of Narcotics, Department of Justice, and Department of Consumer Affairs.[2] The investigators used a total of seven names with two agents using the same name.

Of course, we review the evidence in the light most favorable to the government. *Glasser v. United States*, 315 U.S. 60, 80 (1942). The government established that the following was the mode of operation at Dr. Rosenberg's office: An agent would make an appointment. When he arrived at the office, the doctor's nurse would record his name and address and collect the fee for an office visit. The fee for the first visit was $15 payable in cash; for subsequent visits the charge was $8. The nurse normally took the patient's record into the doctor with the cash clipped to one corner.

At no time did Dr. Rosenberg give any of the agents a physical examination. The agents never voluntarily indicated that they had any medical problem for which they needed medication. For example, when the doctor asked agent Van Diest what was wrong with her, she said that she did not have any problems, that she had been buying pills on the street and wanted a safer source, and that she had heard that she could get them from him. She told Dr. Rosenberg that she wanted some "reds."[3] When Dr. Rosenberg asked her why she wanted them, Ms. Van Diest said that she just liked taking them. The doctor then indicated that he would only give her a month's supply and that the pills could be dangerous. He then asked her if he could do anything

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[2]Dr. Rosenberg argues that he was somehow denied due process because the state investigators turned their information over to the United States Attorney. Such a division of labor is highly desirable so long as it does not deprive a defendant of some constitutional right. There is no suggestion that the California investigators violated Dr. Rosenberg's rights. The doctor was indicted by a grand jury and enjoyed all of the rights and procedural safeguards normally afforded a federal defendant.

[3]A street name for seconal.

else for her and she replied that she would like some "whites."[4] At this point the doctor asked her if she would like to say that she wanted to lose weight. Ms. Van Diest told him that she really did not care. The doctor replied, "Well, we'll say that you would like to lose weight." Dr. Rosenberg gave Ms. Van Diest a prescription for both seconal and dexedrine. At the time of her visit Ms. Van Diest was five feet, six inches tall and weighed 127 pounds. The doctor gave her no kind of physical examination. The testimony of the other agents was similar to that of Ms. Van Diest.

On the basis of the above described evidence, Dr. Rosenberg was charged with violating the federal Controlled Substance Act which provides that

> [e]xcept as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally—(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance.

21 U.S.C. § 841(a)(1). Under the statute a "practitioner" is authorized to prescribe controlled substances. 21 U.S.C. § 829(a)-(b). "Practitioner" is defined as

> a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance *in the course of professional practice or research.*

21 U.S.C. § 802(20) (emphasis added). We interpret this combination of sections 802(20), 829, and 841 to mean that a doctor who acts other than in the course of professional practice is not a practitioner under the Act and is therefore not authorized to prescribe controlled substances. Such a physician is therefore subject to the criminal provisions of the Act contained in section 841(a)(1). Accord, United States v. Badia, 490 F.2d 296, 298 (1st Cir. 1973); United States v. Jobe, 487 F.2d 268, 269 (10th

[4] A street name for dexedrine, a drug that can be used for weight reduction purposes.

Cir. 1973), *cert. denied*, ... U.S. ..... (1974); United States v. Collier, 487 F.2d 268, 271-72 (5th Cir. 1973) ("It is apparent that a licensed practitioner is not immune from the act solely due to his status, . . . but rather, because he is expected to prescribe or dispense drugs within the bounds of his professional practice of medicine.") This same interpretation of the Act was made by the Attorney General:

> A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.

21 C.F.R. § 1306.04(a) (1974).

Our dissenting brother describes the language of section 802 (20) as "vague." However, the terms contained in that section are not vague; courts have often defined the phrase "in the course of professional practice." See pages 5-6 *infra*. Judge Ely's vagueness argument is more accurately viewed as another statement of his contention that Congress did not intend that doctors registered under 21 U.S.C. § 321-29 should be punished under section 841. We reject that contention.

Our examination of the legislative history convinces us that Congress intended section 841(a)(1) to apply to registered doctors. Congress was concerned with the diversion of drugs out of legitimate channels of distribution. The registration system, which requires written records to be maintained of drug transfers from manufacturer to doctor to user was intended to serve as a means of monitoring the flow of drugs in an effort to stop diversion to illegal uses. See H.R. Rep. No. 91-1444, 1970 U.S. Code, Cong. & Admin. News 4566, 4571-72, 4590 [hereinafter House Report]. This legislative intent is manifested in those penalty provisions of the Act that are applicable only to registrants. Those provisions are focused on proper record keeping. See, e.g., 21 U.S.C. §§ 842(a)(1) (use of prescriptions required), 843(a)(1) (use of order forms required).

There is no suggestion in the legislative history that the registration provisions were intended to be a substitute for the Act's general criminal penalties. The legislative history expressly states that the Act "provides severe criminal penalties for persons en-

gaged in illicit . . . sale of controlled drugs primarily for the profits to be derived therefrom." Since this is what Dr. Rosenberg did, the severe criminal penalties contained in section 841 were appropriately applied to him. This conclusion is buttressed by the facts that physicians were subject to the prior federal drug laws, see, e.g., Jin Fuey Moy v. United States, 254 U.S. 189 (1920), and that one of the three purposes of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (of which the Controlled Substances Act is title II) was stated in the preamble to be "to strengthen *existing* law enforcement authority in the field of drug abuse." (emphasis added).

One of the findings of the Congress in enacting the Controlled Substances Act was that "(6) *Federal control* of the intrastate incidents of the traffic in controlled substances *is essential to the effective control* of the interstate incidents of such traffic." 21 U.S.C. § 801(6) (emphasis added). If doctors were not subject to section 841(a)(1) the ability of the federal government to counter drug abuse would be greatly reduced. Congress recognized that "the widespread diversion of [controlled substances] out of legitimate channels in to the illegal market" was a serious problem. House Report at 4572. To stop such abuse, Congress determined that "illegal traffic in drugs should be attacked with the full power of the Federal Government." House Report at 4574. Yet, as the dissent recognizes, any doctor can be registered under the Act as a matter of right if he is allowed to dispense controlled substances under state law. House Report at 4590, 21 U.S.C. § 823(f). Revocation of registration is virtually impossible. See 21 U.S.C. § 824(a). Even conviction of the "technical violations"[5] of section 842 and 843 is foreclosed as long as a doctor complies with the easily fulfilled requirements of prescription writing, etc., contained in the registration sections. See 21 U.S.C. §§ 842, 843, 825, 827-29. Under the reasoning of the dissent a doctor would not even have to pretend to act as a doctor. He could stand on a street corner and sell prescriptions to passersby and yet he

[5]The House Report refers to the violations in section 842(a)(1)-(3) as "technical violations." House Report at 4516. The only other provision expressly applied to registrants is section 843(a)(1), which deals with failures to use the prescribed order forms, another violation properly viewed as technical.

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would be immune from federal prosecution.[6] To leave the federal government powerless to act against such persons would be to "override common sense" and reject the "evident statutory purpose of Congress.[7]

Moreover, we note that the dissent's interpretation of the Act would make superfluous one of its main reform provisions. Title I of the Act deals with rehabilitation of addicts. Section 4 of that title provides that the Secretary of Health, Education, and Welfare, in consultation with the Attorney General, "shall determine the appropriate method of professional practice in the medical treatment of narcotic addiction." This section was adopted in light of Congress' awareness that there had been "criminal prosecution of physicians whose methods of prescribing narcotic drugs have not conformed to the opinions of Federal prosecutors." House Report at 4581. The committee evidenced no intention to restrict

[6]We do not understand the dissent's suggestion that veterinarians would somehow be restricted by the Act. They are practitioners, 21 U.S.C. § 802(20), who can register under the Act. Once registered, there is nothing in 21 U.S.C. §§ 842(a)(1)-(2), (b), 843(a)(1), which would prevent them from hawking pills to humans. The only limitation imposed by the Act with regard to registration is that the drugs prescribed must be covered by the registration. 21 U.S.C. § 842(a)(2). Under the Act no limitation exists as to whom a registrant can prescribe drugs. Since the veterinarian's prescription would enable a human to buy drugs, the human could use the drugs.

[7]The Supreme Court has written that

> [t]he canon in favor of strict construction [of criminal statutes] is not an inexorable command to override common sense and evident statutory purpose. . . . [n]or does it demand that a statute be given the "narrowest meaning"; it is satisfied if the words are given their fair meaning in accord with the manifest intent of the lawmakers.

United States v. Brown, 333 U.S. 18, 25-26 (1948).

In this regard it is interesting to note that the Senate report on the Narcotic Addict Treatment Act of 1974, Pub. L. No. 93-281, 88 Stat. 124, discussed Dr. Moore's conviction with approval. (Dr. Moore was the doctor involved in United States v. Moore, 505 F.2d 426 (1974) where the D.C. Circuit held that section 841 cannot be applied to registered doctors). There was *no* indication that the conviction was a violation of Congress' scheme of drug abuse control. If Congress had not intended doctors to be subject to section 841, one would have expected that to have been pointed out by some member of the Senate Judiciary Committee, especially since all but two of its members in 1974 had been on the committee in 1970.

such prosecutions. Indeed they seemed to think that they would continue, but that some standards of professional practice should be established so that "[t]hose physicians who comply with the recommendations made by the Secretary will no longer jeopardize their professional careers by accepting narcotic addicts as patients." House Report at 4581. If a registered doctor was not subject to the penalties of section 841, section 4 of title I would be superfluous because no federal action could be taken against such a doctor in any event.

The above considerations, taken altogether with the fact that there is no statement in the legislative history that indicates that doctors are not to be subject to section 841, lead us to conclude that section 841 was appropriately applied in this case.

In dissent Judge Ely relies principally on a decision by the District of Columbia Circuit, United States v. Moore, 505 F.2d 426 (1974), *cert. granted*, ... U.S. ..... (1975), which held that doctors registered under the Act, see 21 U.S.C. §§ 821-29, are exempt from the penalty provisions of 21 U.S.C. § 841(a)(1). The court in *Moore* gave essentially three reasons for its decision.

First, it noted that section 822(b) provides that "[p]ersons registered by the Attorney General under this subchapter to distribute or dispense controlled substances are authorized to . . . distribute or dispense such substances . . . to the extent authorized by their registrations and in conformity with the other provisions of this subchapter." It concluded that this passage was a blanket authorization to dispense drugs that exempted registered doctors from section 841. However, according to the legislative history that section was added merely to "make it clear that persons registered under this title are authorized to deal in or handle controlled substances." House Report at 4606. This section was not part of the original bill, so it can scarcely be called an essential part of the registration scheme. Indeed, it only says that registrants are authorized to do what the Act permits them to do. Thus, in the absence of any explicit direction from Congress, we think it inappropriate to interpret that section to work a major change in the prior enforcement pattern of drug laws which heretofore have not exempted doctors who acted outside the scope of their professional practice from the penal provisions that apply generally to all persons.

The second factor stressed by the *Moore* majority is that while certain of the penalty provisions found in sections 842 and 843 specifically refer to "registrants," that word does not appear in section 841. 505 F.2d at 430. From this the *Moore* court seemed to conclude that registered doctors are subject only to those penalty provisions which specifically refer to registrants. This is clearly a misreading of the statutory scheme. Sections 841, 842, and 843 each apply to all persons.[8] Whenever Congress wanted to limit the scope of a provision's coverage it specifically so indicated. See, e.g., 21 U.S.C. §§ 842(a)(1)-(3), (b), 843(a)(1). In doing so Congress evidenced complete awareness of the distinction between registrants and persons. However, it still chose to apply all of the remaining penalty provisions of the Act to any "person." See 21 U.S.C. §§ 841, 842(a)(4)-(8), 843(a)(2)-(5), (b).

We see no reason to construe the statute's clear language in those eleven sections to mean "person other than a registrant." Section 843(a)(3), for example, applies to any person who "acquire[s] or obtain[s] possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge"—a crime obviously committable by any person—registered doctor or otherwise. Yet the reasoning of the D.C. Circuit would seem to compel a holding that registrants were not subject to the provision because the word "registrant" is not included therein. We see no basis for such a result. Congress understood that persons included registrants (see, e.g., 21 U.S.C. § 842((a)(2): "any person— . . . (2) who is a registrant"), and it made 21 U.S.C. § 841(a)(1) apply to "any person."

Finally, the court in *Moore* refused to intrepret the 1970 Act in light of the Harrison Act, 505 F.2d at 431-34, because the new

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[8]Section 841 applies to any person unless he is "otherwise authorized" to distribute drugs. We have already indicated that such authorization is contained in section 829, which permits practitioners to write prescriptions. It is suggested by the *Moore* court that this language could also refer to section 822(b). However, since that section only authorizes a registered doctor to act in conformity with the Act, it is still necessary to refer to section 829. Since a doctor acting outside the course of professional practice is not a practitioner in our view, such a doctor would not be able to avail himself of section 829, and thus would violate section 841 if he made drugs available to other persons by prescription or otherwise.

act is "fundamentally different." The major difference, however, is only complexity. The Controlled Substances Act was intended to replace the some 50 pieces of legislation dealing with drugs that had been enacted by Congress since 1914. House Report at 4571. In any event, the legislative history of the Act shows that section 841 was meant to apply to drug traffickers. When a doctor acts as Dr. Rosenberg did in this case, he can appropriately be called a trafficker in drugs. While it is difficult to convict a doctor under this standard, a combination of sections 841, 829, 802(20) certainly allows such conviction. Indeed, Congress seemed to recognize that this Act could result in the conviction and punishment of a doctor, just as under the Harrison Act, if the doctor failed to comply with certain standards of professional practice. *See* House Report at 4581.

Thus, we conclude that the Controlled Substances Act, including 21 U.S.C. § 841, on its face, can be applied to registered doctors. The reasons advanced by the dissent and the *Moore* court are at best inconclusive of Congress' intent. Since there are other indications in the Act and in the legislative history that Congress intended section 841 to apply to registered doctors, we hold that the Act does, and was intended by Congress to, apply to the registered doctors acting outside the course of professional practice. For further support of this view, see United States v. Green, No. 74-1428, Slip Op'n at 8-13 (7th Cir., Feb. 27, 1975), 43 U.S.L.W. 2385; United States v. Moore, 505 F.2d at 444-58 (MacKinnon, J., dissenting).

We turn now to the arguments raised by Dr. Rosenberg in his various briefs filed in this court.[9] First, he argues that he was convicted of violating a regulation issued by the Attorney General rather than the Act itself. He suggests that this would violate the doctrine of separation of powers because the Department of Justice has no statutory authorization to issue regulations that

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[9]Apparently only Dr. Moore has thought that section 841 did not apply to registered doctors. This argument is not among the many arguments made by Dr. Rosenberg, and it does not seem to have been made before any other court, see United States v. Moore, 505 F.2d 426, 434 n.44 (D.C. Cir. 1974). The fact that virtually everyone has assumed that registered doctors are subject to section 841 is some evidence that Congress intended them to be.

create new criminal offenses.[10] The indictment against Dr. Rosenberg charged him with distributing pills not "in the usual course of professional practice" and not "for any legitimate medical research purposes." The first quoted phrase is similar to the statutory language, see 21 U.S.C. § 802(20); the second is similar to the language in the regulation, see 21 C.F.R. § 1306.04(a) (1974). The indictment referred only to 21 U.S.C. § 841(a)(1) and 18 U.S.C. § 2(b) (general provision on liability of principals for criminal acts); no mention was made of any regulation. Dr. Rosenberg seems to argue that these two phrases have different meanings and that he was convicted of violating the regulation. We disagree.

The two phrases in the indictment have essentially the same meaning. At no time did Judge Gray instruct the jury (or even suggest to the jury) that there were two separate ways in which the statute could be violated. In his instructions to the jury on what he called the "principal issue" Judge Gray charged that

> (t)he law makes it unlawful for any person to distribute a controlled substances except a practitioner who causes the controlled substance to be *distributed in the course of professional practice*. If this doctor was causing the controlled substance to be prescribed while acting as a doctor *in the course of his professional practice*, then there's no violation. However, if he was not acting in good faith as a doctor, but simply pushing pills, as counsel has said, then he does not come within the exception, and the law is violated.

The trial judge stressed that the jury had to look into Dr. Rosenberg's mind to determine whether he prescribed the pills for what he thought was a medical purpose or whether he was passing out the pills to anyone who asked for them. He in no way indicated that the jury could find Dr. Rosenberg guilty if it found that he either acted not in the course of his professional practice or not for legitimate medical reasons. In fact, as the extract from the judge's charge demonstrates, he laid out the issue as whether the doctor had acted not in the course of professional

[10]The Attorney General does have the power to "promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter." 21 U.S.C. § 871(b).

practice, which is the statutory language. While the trial judge later used the phrase "good faith for legitimate medical treatment in the usual course of his professional practice," it seems clear that the trial judge was simply elaborating on the statutory language, as he did in other ways on different occasions.[11] We find it difficult to understand how Dr. Rosenberg can argue that he was not not acting for legitimate medical reasons yet was acting in the course of his professional practice.

Dr. Rosenberg next argues that the phrase "in the course of professional practice" is so vague that it violates the due process clause of the Fifth Amendment. The Supreme Court has recently held that "(t)o avoid the constitutional vice of vagueness, it is necessary, at a minimum, that a statute give fair notice that certain conduct is proscribed." *Rebe v. Waskington*, 405 U.S. 313, 315 (1972) (per curiam). Here we think that the statute does give such fair notice. This language has been in the statute books since 1914 and no one has ever had problems with its interpretation. The language clearly means that a doctor is not exempt from the statute when he takes actions that he does not in good faith believe are for legitimate medical purposes.

The Supreme Court had several occasions to interpret this language when it was used in the Harrison Narcotics Law § 2, 38 Stat. 785. For example, in *Jin Fuey Moy v. United States*, 254 U.S. 189, 194 (1920) (emphasis added), the Court noted that "the phrases 'to a patient' and 'in the course of his professional practice only' are intended to confine the immunity of a registered physician, in dispensing the narcotic drugs mentioned in the act, strictly within *the appropriate bounds of a physician's professional practice*, and not to extend it to include a sale to a dealer or a distribution intended to cater to the appetite or satisfy the craving of one addicted to the use of the drug." Two years later the Court again explained the meaning of the statute: "[T]he purpose of the exception is to confine the distribution of these drugs to the *regular and lawful course of professional practice*." *United States v. Behrman*, 258 U.S. 280, 287 (1922) (emphasis added). In another case the Court said that "[t]he disputed question was whether the defendant issued the prescrip-

[11] This interpretation is supported by language in the Supreme Court cases discussed *infra*.

tions *in good faith in the course of his professional practice.*" *Boyd v. United States*, 271 U.S. 104, 105 (1926) (emphasis added).

The ease and consistency with which courts have interpreted this language convinces us that it is not vague. See also *United States v. Collier*, 478 F.2d 268, 271-72 (5th Cir. 1973); *United States v. Larson*, 507 F.2d 385 (9th Cir. 1974). Moreover, it is difficult to see how the language can be made more precise and at the same time ban the undesirable conduct on the part of physicians which Congress intended to make illegal and subject to sanctions.

Third, Dr. Rosenberg attacks the constitutionality of the federal drug laws. He urges that they violate the Tenth Amendment.[12] Specifically Dr. Rosenberg argues that the determination of whether or not he was acting in the course of his professional practice must be determined by the state of California because "direct control of medical practice in the States is beyond the power of the Federal Government." *Linder v. United States*, 268 U.S. 5, 18 (1925). He also argues that the language of the statute makes it clear that Congress intended that the federal government rely on such a state determination. These arguments are singularly unpersuasive.

As the doctor admits in his brief, the Tenth Amendment is generally viewed as stating a truism. "From the beginning and for many years the amendment has been construed as not depriving the national government of authority to resort to all means for the exercise of a granted power which are appropriate and plainly adapted to the permitted end." *United States v. Darby*, 312 U.S. 100, 124 (1941). The authority of Congress to control the dispensation of narcotics or other dangerous drugs under a taxing scheme was expressly upheld in *United States v. Doremus*, 249 U.S. 86 (1919).[13] While the current drug laws are not part of a revenue-raising scheme, we have no doubt that Congress has the power to regulate drugs under the Interstate Commerce Clause of

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[12]The Tenth Amendment states, "The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people."

[13]*Doremus* was discussed and cited with approval in *Linder*, the case relied upon by defendant. *Linder v. United States*, supra, at 19.

the Constitution. *United States v. Collier*, 478 F.2d 268, 272-73 (5th Cir. 1973). The statute involved in this case is constitutional.[14]

Fourth, Dr. Rosenberg argues that the federal drug control statute violates due process because it establishes a presumption of guilt. The doctor focuses on 21 U.S.C. § 885(a)(1) which provides that

> [i]t shall not be necessary for the United States to negative any exemption or exception set forth in this subchapter . . . in any trial, hearing, or other proceeding under this subchapter, and the burden of going forward with the evidence with respect to any such exemption or exception shall be on the person claiming its benefit.

We find nothing wrong with this provision. It is a common provision in criminal statutes that contain many exemptions or exceptions. Without such a provision the government would be required to waste valuable court time disproving arguments that a defendant did not and could not conceivably make.

The important fact is that the quoted provision does not shift the burden of proof. Once a defendant presents a claim that he falls within the exemption, the government must prove beyond a reasonable doubt that the accused does not fall within it. In this case a reading of the trial judge's instructions to the jury leaves no doubt that the government was required to prove beyond a reasonable doubt that Dr. Rosenberg was not a physician acting

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[14]The doctor argues that the cases upholding the constitutionality of drug laws are distinguishable because the defendants in those cases had prescribed excessive amounts of drugs and were clearly not acting in the course of professional conduct. He claims that since his prescriptions were within the legal quantity limits for such prescriptions and since it was not clear that he was acting other than in the course of his professional conduct, the Constitution somehow requires that the state of California must first find his acts were unauthorized before federal prosecution is permissible. We do not agree. If the Constitution allows the federal government to regulate the dispensation of drugs, it allows it to do so in every case, and not just where more than a certain quantity of drugs are involved. It would be impractical and unheard of first to determine whether a physician's conduct was or was not sufficiently egregious in order to decide whether federal or state-federal prosecution was appropriate. The question of whether federal criminal laws have been violated is a federal issue to be determined in federal courts.

in the course of his professional conduct. 21 U.S.C. § 885(a)(1) is clearly constitutional. *United States v. Collier, supra,* at 273.

Fifth, the doctor argues that there was insufficient evidence to sustain a guilty verdict. In addition to the testimony outlined above, there was additional evidence to support the conviction of the defendant. For example, the agents testified, among other things, that when they paid their money, but did not receive prescriptions, the money was refunded; that they indicated to the doctor that they were giving some of the prescribed pills to other people, and that they were also obtaining pills from other doctors. In addition, the government offered the testimony of a medical expert, who stated that proper professional practice required that a doctor give a physical examination before prescribing the drugs involved here for a patient he had never seen before. The expert also indicated that dexedrine has only limited uses and in the area of weight control is primarily used to help grossly obese people lose weight. In rebuttal, Dr. Rosenberg offered only his own testimony.

We think that the testimony of the expert and the facts outlined by the agents are sufficient to sustain the defendant's conviction. Indeed, the jury could decide for itself, on the basis of the facts shown and without any expert testimony, that Dr. Rosenberg was not acting in the course of his professional practice. *United States v. Larson,* 507 F.2d 385 (9th Cir. 1974); *United States v. Badia,* 490 F.2d 296 (1st Cir. 1973); *United States v. Bartee,* 479 F.2d 484 (10th Cir. 1973). There was ample evidence to support the verdict of the jury.

Sixth, Dr. Rosenberg argues that his conviction should be overturned because his medical files were used against him in violation of his Fifth Amendment right against self incrimination.[15] The validity of the doctor's arguments turns in the first instance on whether or not he had a protected interest in his prescription records. The general rule is that if records are required to be main-

[15]On September 24, 1973, Dr. Rosenberg was served with a grand jury subpoena for his patient records as they related to the dispensation of narcotic substances to several named persons. He supplied the records for all but one of the patients covered by the subpoena. On a motion to suppress the records as evidence Dr. Rosenberg claimed that he was tricked into surrendering them. The district court, however, found that he was not tricked.

tained by law then a defendant cannot assert a privilege against self incrimination with respect to those records. *Shapiro v. United States*, 335 U.S. 1 (1948).

A California statute requires that records of prescriptions for the drugs involved in this case be kept for two years. Cal. Health & Safety Code § 11191. While the statute does not expressly provide that records shall be open to inspection by state officials,[16] we think that the only purpose for the record-keeping requirement is to aid in the enforcement of the drug control statutes.

In *Grosso v. United States*, 390 U.S. 62, 68 (1968), the Supreme Court laid down three criteria to be used in determining the applicability of the official-records exception to the Fifth Amendment. The first is that the purpose of the record-keeping requirement is essentially regulatory. Second, that the records are customarily kept, and third, that the records have public aspects. These criteria are clearly met in this case. Cf. *United States v. Resnick*, 488 F.2d 1165 (5th Cir. 1974). Dr. Rosenberg's Fifth Amendment rights were not violated.

Finally, Dr. Rosenberg argues that he was improperly indicted for unlawfully "distributing" a controlled substance. He contends that he should have been charged with unlawfully "dispensing" a controlled substance. We find no merit in this argument. *United States v. Black*, No. 73-3003 (9th Cir., March 11, 1975); *United States v. Badia*, 490 F.2d 296 (1st Cir. 1973); but see *United States v. Leigh*, 487 F.2d 206 (5th Cir. 1973). We have previously upheld convictions for distribution in similar circumstances. *United States v. Cosby*, 500 F.2d 405 (9th Cir. 1974); *United States v. Larson*, supra.[17]

We have considered the other arguments made by Dr. Rosenberg and find them to be without merit.

Affirmed.

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[16]The statute at one time expressly provided that the records were to be open to such inspection.

[17]Since the defendant raised this argument only as an afterthought in a brief filed after the argument, he can scarcely claim that he was not fully apprised of the charges against him. See *The Schooner Hopper v. United States*, 11 U.S. 389, 394 (1813).

ELY, Circuit Judge (Dissenting):

I respectfully dissent.

In my view, the clear holding of *United States v. Moore*, 505 F.2d 426 (D.C. Cir. 1974), *cert. granted*, ... U.S. ....., 43 U.S.L.W. 3445 (U.S., February 18, 1975), completely destroys any statutory basis for Dr. Rosenberg's convictions. *Moore* holds, with one judge dissenting, that Congress did not intend to subject licensed, registered physicians to the harsh, generally-applicable penal sanctions of 21 U.S.C. § 841 for alleged offenses arising from their prescribing controlled substances that have accepted uses in medical treatment. My intensive review of the complete structure of Title II of the Drug Abuse Prevention and Control Act of 1970 (hereinafter "the Act" or "the 1970 Act"), 21 U.S.C. §§ 801 *et seq.*, in which section 841[1] appears, convinces me, beyond question, that the conclusion reached by the majority in *Moore* is correct and that, hence, the majority's disposition of the present appeal cannot be logically sustained.

I. Statutory Analysis

In the 1970 Act, Congress undoubtedly intended to strike a hard blow at drug traffickers. Nevertheless, Congress had before it a competing consideration, which is listed first among its findings and declarations:

> Many of the drugs included within this [Act] have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people.

21 U.S.C. § 801(1). To assure the availability of such drugs for the nation's medical needs and yet to prevent, insofar as possible, the diversion of such drugs into illegitimate channels, Congress created, in Part C of the Act, 21 U.S.C. §§ 821-829, that which Congress termed ". . . a 'closed' system of drug distribution for legitimate handlers." H.R. Rep. No. 1444, 91st Cong., 2d Sess. 6 (1970) (1970 U.S. Code Cong. & Admin. News 4571-72). Part C establishes a comprehensive scheme for registering and controlling the physicians, pharmacists, pharmaceutical manu-

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[1] All sections of the Act are numbered as they appear in Title 21, United States Code.

facturers, research scientists, and others whose professional duties require that they be licensed or otherwise legally authorized to manufacture or dispense controlled substances.

Within Part C, section 822(a) requires that physicians and the other professionals within the scope of the "closed system" register annually with the Attorney General. As to physicians, the Attorney General must grant such registration *pro forma*. He has absolutely no discretion to refuse to register a physician who is already licensed to dispense controlled substances by the state in which the physician practices.[2] 21 U.S.C. § 823(f). Once a physician is registered, the Act makes clear that he is fully authorized to administer or dispense controlled substances to the extent permitted by his registration, 21 U.S.C. § 822(b),[3] and the only restriction the Act applies to the registrations of physicians is that such registrations confer no authority whatsoever to deal in those controlled substances that have no accepted values in medical treatment. Medically worthless drugs, such as heroin, most of the other opiates, and LSD, are listed in the Act's Schedule I, 21 U.S.C. § 812(b)(1); and section 823(f) expressly limits the registrations authorized for physicians to the controlled substances listed in Schedules II, III, IV, and V, all of which have accepted medical uses.[4] *See* 21 U.S.C. §§ 812(b)(2)-812(b)(5).

Congress included within Part C a system of administrative controls over physicians and the other members of the "closed

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[2]Dr. Rosenberg was licensed as a physician by the State of California. The statute defining the scope of a licensed physician's practice in California, Cal. Bus. & Prof. Code § 2137, reads as follows:

> The physician's and surgeon's certificate authorizes the holder to use drugs or what are known as medical preparations in or upon human beings and to sever or penetrate the tissues of human beings and to use any and all other methods in the treatment of diseases, injuries, deformities, or other physical or mental conditions.

[3]The 1970 Act was derived principally from the House bill. As to section 822(b), the House committee report states: "The committee inserted this subsection to make it clear that persons registered under this title are authorized to deal in or handle controlled substances." H.R. Rep. No. 1444, 91st Cong., 2d Sess. 38 (1970) (1970 U.S. Code Cong. & Admin. News 4606).

[4]The charges against Dr. Rosenberg were based on prescriptions he had written for controlled substances listed in Schedules II, III, and IV.

system." There are, for example, extensive record-keeping requirements, and section 829 sets forth the detailed requirements pertaining to doctors' "prescriptions" for the controlled substances in Schedules II, III, IV, and V. Physicians who abuse their authority to dispense controlled substances are subject to a range of specialized sanctions. Of course, the ultimate and undoubtedly most effective sanction against a physician who uses his professional status merely to traffic in drugs is that his state's licensing authority may revoke his medical license. Upon such revocation, the physician's registration under Part C is also revoked; but there are also other reasons for which the Attorney General may suspend or revoke a Part C registration. 21 U.S.C. § 824. In addition, two later sections of the Act, 21 U.S.C. §§ 842 and 843, identify a number of "unlawful acts" and prescribe penalties, both civil and criminal, that apply specifically to "registrants" or "persons who are subject to the registration requirements of Part C."[5]

In contrast, section 841, the statute under which Dr. Rosenberg stands convicted, contains neither the word "registrant" nor the phrase "persons subject to the requirements of Part C." Rather, its application is limited by the introductory phrase, "[e]xcept as authorized by this subchapter," and the only "exception" to which this phrase logically can apply is that created for the "closed system" by the registration scheme of Part C. The phrase "as authorized by this subchapter" in section 841 specifically reflects the "[p]ersons registered . . . are authorized . . ." language of section 822(b) in Part C.

There is no language whatsoever in either section 841 or in Part C that supports the view that a physician loses the exception granted by his registration under Part C and thereby becomes subject to the penal sanctions of section 841 by prescrib-

[5]The criminal penalties provided for registrants in sections 842 and 843 are not as great as those provided in section 841, the statute generally applicable to narcotics traffickers; nevertheless, the sections 842 and 843 sanctions are substantial. Section 842 authorizes a maximum punishment of one year's imprisonment and a $25,000 fine. Section 843 provides for imprisonment for a period as long as four years, plus a maximum fine of $30,000.

ing medically-accepted drugs for what a jury might thereafter determine to be an improper purpose.[6] Dissenting in *Moore*, Judge MacKinnon writes that Congress's use in section 841 of the verb "dispenses," along with the other verbs "manufactures," "distributes," and "possesses," indicates that Congress intended to subject physicians to 841 liability, since Part C professionals are the only one who may "dispense," as that term is defined in section 802(10). Judge MacKinnon further suggests that since Congress provided in section 824(a) that the Attorney General may revoke a practitioner's Part C registration if the practitioner is convicted under the Act for a felonious offense, Congress must have intended that section 841, the Act's only felony provision, should apply. *United States v. Moore, supra* at 451, 454 (MacKinnon, J., dissenting).

As to both provisions, Judge MacKinnon overlooks the explanation that registered physicians have no authority to deal in Schedule I controlled substances. Consequently, a physician may illegally "dispense" Schedule I controlled substances and may be prosecuted under the felony provisions of section 841 for doing so. Furthermore, the provisions cited by Judge MacKinnon apply not only to physicians, but also to such other professionals as pharmacists and veterinarians whose state licenses and Part C

[6]The majority's argument that Title I, section 4 of the Act, 42 U.S.C. § 257a, which focuses on the development of standards for medical treatment of narcotics addicts, stands as evidence that Congress intended that the general criminal penalties of section 841 should apply to registered physicians has already been rebutted in *United States v. Moore*, 505 F.2d at 433-34. I note in addition, however, that on its face, 42 U.S.C. § 257a says nothing whatsoever about any criminal sanctions applicable to physicians who fail to follow the standards promulgated by the Secretary of Health, Education and Welfare. Rather, the Secretary's role under the statute appears primarily to relate to research and the advancement of generally-available scientific knowledge concerning the treatment of narcotics addiction. Furthermore, the majority is incorrect in asserting that under my reading of the Act, any special provision concerning the treatment of addicts would be superfluous since a physician could never be prosecuted for providing drugs simply to maintain an addiction. The majority overlooks, or chooses to disregard, the significant point, made earlier, that Part C confers absolutely no authority on registered physicians to deal in Schedule I controlled substances. Consequently, Part C would provide no protection to a doctor who "dispenses" heroin to a heroin addict.

registrations "authorizes" a narrower scope of activities than that authorized for licensed physicians. Since the Attorney General issues a Part C registration to a practitioner solely on the basis of the practitioner's state professional license, 21 U.S.C. §§ 802 (20), 823(f), the registration could authorize the practitioner to deal in controlled substances only to the extent permitted by the state license. For example, Part C would provide no immunity from section 841 for a veterinarian who "dispenses" Schedule II controlled substances to human patients, since the veterinarian's state license would not authorize him to undertake such treatments. If this does not clarify the misunderstanding expressed in one of the majority's footnotes in respect to the point here discussed, then I am unable to eliminate that misunderstanding.

After studying the Act in its entirety, I am impelled to the conclusion that Congress chose not to place a physician in jeopardy of the severe criminal sanctions of section 841 on such a slender thread as a jury's later conclusion that the physician has prescribed a drug with accepted medical values for an improper purpose. Congress obviously intended for any such abuses to be halted through professional or administrative action and through imposition of the less-severe criminal and civil sanctions provided in sections 842 and 843. *Accord, United States v. Moore, supra.*

II. Vagueness

Rejecting the careful statutory analysis of *Moore*, my Brothers choose instead to take our Court further down the tortured and mistaken path first chosen by the Fifth Circuit in *United States v. Collier*, 478 F.2d 268 (5th Cir. 1973). In doing so, the majority violates one of the cardinal principles of statutory construction—that courts must ascertain the meaning of a doubtful statute by looking to the statutory enactment as a whole, not merely to isolated words and phrases. *See, e.g., Richards v. United States*, 369 U.S. 1, 11 (1962). That my Brothers may travel in excellent company, *see United States v. Bartee*, 479 F.2d 484 (10th Cir. 1973); *cf. United States v. Larson*, 507 F.2d 385 (9th Cir. 1974);[7] *United States v. Badia*, 490 F.2d 296 (1st

[7]I was a member of the panel of this Court that decided *Larson*, wherein we unanimously affirmed the section 841 conviction of a licensed physician on facts similar to those presented here. Because of the more

Cir. 1973), does not, despite their protests to the contrary, save them from their wrongful detour.

In a nutshell, the majority's reasoning is as follows: The "[e]xcept as authorized by this subchapter" proviso in section 841 refers to section 829, in Part C of the Act, which provides for the dispensing of controlled drugs on the basis of a prescription written by a "practitioner." And, a physician is a "practitioner," as that term is used in section 829 and defined in section 802(20), only when the prescriptions he writes are ". . . in the course of professional practice," 21 U.S.C. § 802(20), a phrase that the majority reads to mean "in the course of a *proper, usual*, or *legitimate* professional practice."

As the majority plainly recognizes, the validity of their view concerning the applicability of section 841 to registered physicians depends entirely on the correct reading of the phrase, ". . . in the course of professional practice . . . ," which appears not in the penal statute itself, but in the Act's general definition of the term "practitioner." In pertinent part, that definition reads:

> The term "practitioner" means a physician . . . licensed by . . . the jurisdiction in which he practices . . . to . . . dispense a controlled substance in the course of professional practice . . ."

21 U.S.C. § 802(20).

One's first logical reaction after reading the phrase ". . . in the course of professional practice . . . ," in the context in which it is used, must be that Congress included it within the definition in order to specify the type of license that qualifies a physician for the "practitioner" designation. Once a physician has received such a license from his state, it seems obvious, under the definition, that he is, and remains so long as he retains his license, a "practitioner." At the time of Dr. Rosenberg's alleged offenses, he was duly and regularly licensed by the State of California ". . . to . . . dispense a controlled slbstance in the course of professional practice . . . ;" therefore, Dr. Rosenberg was a "prac-

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searching inquiry prompted by the briefs and arguments in this case and by the decision in *Moore*, I am now convinced that our decision in *Larson* was wrong. I regret, of course, that I cannot now undo my judicial mistake in respect to *Larson*.

titioner."[8] The majority's different construction of the phrase, which is that the phrase has a chameleon-like effect that operates to deprive a physician of the status of "practitioner" whenever the physician acts outside the scope of what a jury of laypersons believes to be a proper, usual, or legitimate professional practice, seems, with all due respect, quite strained. The majority adopts its interpretation despite the well-established rule that penal statutes must be construed strictly in favor of the accused. *See e.g., Smith v. United States*, 360 U.S. 1, 9 (1959).

Assuming, *arguendo*, however, that Congress did intend to give the phrase the meaning the majority attributes to it, Congress has, without doubt, used language that is ". . . so vague that men of common intelligence must necessarily guess as to its meaning and differ as to its application." *Connally v. General Construction Co.*, 269 U.S. 385, 391 (1926). The Constitution plainly condemns such vagueness, especially in criminal statutes. *See, e.g., Smith v. Goguen*, 415 U.S. 566 (1974). One of the principal vices of vagueness in penal statutes is, as here, ". . . the treachery they conceal . . . in determining what persons are included . . . ." *United States v. Cardiff*, 344 U.S. 174, 176 (1952).

The majority apparently concedes that the phrase, ". . . in the course of professional practice . . . ," is, on its face, too imprecise to support a criminal conviction. But the majority concludes that the phrase's meaning has been clarified by several old decisions of the Supreme Court that construe what the majority asserts to be similar language in the now-repealed Harrison Anti-Narcotic Act, ch. 1, 38 Stat. 785, enacted in 1914. I submit that the majority's reliance on the Harrison Act cases is obviously misplaced.

The legislative history of the 1970 Act reveals that Congress intended the new Act to be a complete revision of the criminal provisions of the federal narcotics laws. *See United States v. Moore*, *supra* at 431-34. Without question, Congress sought completely to abrogate the criminal provisions of the old Harrison Act. This fact alone should stand as a clear warning against

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[8] *See* the relevant California statute, quoted *supra* n.2.

any blind reliance on the Harrison Act precedents in interpreting the new Act's provisions.

But there is an additional reason for not doing what the majority has done with the Harrison Act decisions. In those cases the Supreme Court construed a proviso that appeared directly in the penal section of the Harrison Act and which read:

> Nothing contained in this section shall apply—
>
> (a) To the *dispensing* of any of the aforesaid drugs *to a patient* by a physician . . . registered under this Act in the course of his professional practice *only*.

Ch. 1, § 2, 38 Stat. 786. (Emphasis added.) Yet the majority seeks to employ the Supreme Court's opinions to clarify the following phrase from the 1970 Act: ". . . licensed . . . to dispense . . . a controlled substance in the course of professional practice . . . ." 21 U.S.C. § 802(20). The differences between the two statutes hardly require elaboration. The new Act does not contain the very elements that give the Harrison Act proviso its clear meaning—the phrase "to a patient" and the small but powerful word "only." *These are the precise portions of the Harrison Act proviso upon which the Supreme Court decisions cited by the majority rely. United States v. Behrman*, 258 U.S. 280, 288 (1922);[9] *Jin Fuey Moy v. United States*, 254 U.S. 189, 194 (1920). Furthermore, the Harrison Act proviso spoke in terms of "dispensing," which is the way that the majority, in effect, re-

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[9]In *Behrman*, the Supreme Court reversed a District Court's dismissal of an indictment that charged a physician with prescribing large quantities of heroin and morphine to a person known by the physician to be an addict for the allegedly illegal purpose of maintaining the addict's habit. The Supreme Court held that the indictment stated an offense against the physician under the Harrison Act. Despite the language of the Harrison Act proviso pertaining to physicians, which would establish Dr. Behrman's criminal liability far more clearly than could the critical language in the 1970 Act, Justices Holmes, Brandeis, and McReynolds dissented. The dissenters' comments, written by Mr. Justice Holmes, are fully applicable to the result the majority reaches in the instant case.

> It seems to me impossible to construe the statute as tacitly making such acts, however foolish, crimes, by saying that what is in form a prescription and is given honestly in the course of a doctor's practice, and therefore, so far as the words of the statute go, is allowed in terms, is not within the words, is not a prescription and is not given

writes the new Act, even though, as I have hitherto thoroughly demonstrated, the operative verb in the new Act is "licensed."

Actually, the Harrison Act cases support my interpretation of the 1970 Act, rather than the wholly unwarranted interpretation of the majority. My Brothers assert that Congress intended in the 1970 Act to continue the same criminal liability for registered physicians that so clearly existed under the Harrison Act. If this is true, the majority might have undertaken an explanation of why Congress chose in the new Act, in the face of consistently favorable Supreme Court interpretations of the Harrison Act proviso, to alter drastically the language of the proviso by deleting "to a patient" and "only," to cast the proviso in terms of "licensing" instead of "dispensing," and to move the proviso from the penal provision to the general definitions section of the Act.

Finally, in further support of its interpretation of the phrase, ". . . in the course of professional practice . . . ," the majority relies on an administrative regulation, 21 C.F.R. § 1306.04(a), which was issued by the Attorney General. The majority's reliance again is misplaced. To me, it is inconceivable that an unconstitutionally vague and ambiguous penal statute can be cured by a regulation issued by the prosecuting agency. Furthermore, the cited regulation has no relationship whatsoever to the definition of "practitioner" in section 802(20), in which the critical statutory phrase appears. Rather the Attorney General promulgated the regulation pursuant to his general statutory authority under section 821 to make rules for the "closed system" established in Part C. Specifically, the regulation applies to section 829, the portion of Part C that establishes the administrative requirements pertaining to doctors' prescriptions. A physician who violates one of the regulations pertaining to Part C possibly subjects himself to the administrative and professional sanctions contemplated in Part C and to the specialized provisions for Part C registrants in sections 842 and 843. The majority, however, and correctly in my view, does not contend that violation

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in the course of practice, if the Court deems the doctor's faith in his patient manifestly unwarranted. It seems to me wrong to construe the statute as creating a crime in this way without a word of warning. 258 U.S. at 290 (Holmes, J., dissenting).

of such a regulation, alone, could subject a physician to prosecution under the general penal provisions of section 841.[10]

Rather, the majority relies on the Attorney General's regulation, along with the Supreme Court's Harrison Act precedents, to eliminate the ambiguity encountered in the section 802(20) phrase, ". . . in the course of professional practice . . . ." I think that, at most, the majority should consider the regulation as an admission by the executive officer responsible for administering the Act that the crucial phrase, as it appears in the statute, is too vague to support the criminal liability that the Government asserts.

The question posed by the ambiguity in the section 802(20) phrase is whether Congress intended to subject licensed physicians to criminal prosecution under section 841 for dispensing medically-approved controlled substances in an allegedly unprofessional manner. To permit the Attorney General to answer that question, in the guise of issuing an "interpretive" regulation, would be, in my view, to countenance an intolerable violation of the doctrine of separation of powers. By such a regulation, the Attorney General could subject a class of persons to criminal liability under a Congressional act wherein, at best, it is unclear whether Congress intended that such liability should attach. *See Viereck v. United States*, 318 U.S. 236 (1943); *cf. Reid v. Covert*, 354 U.S. 1, 38-39 (1957) (Opinion of Black, J.).

In conclusion, I firmly hold that Dr. Rosenberg's convictions simply cannot be sustained on the basis of the majority's reasoning. My Brothers, I think, have subconsciously responded to a realistic concern that the severe sanctions of section 841 are necessary to prevent some licensed physicians from degrading themselves and damaging society by falling into the category of common drug pushers. I can agree that such a possibility exists and, indeed, even that the majority's legitimate concern may be

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[10]The majority does note that section 871(b) grants the Attorney General authority to promulgate rules and regulations for the effective administration of the Act. With this I do not quarrel. It is clear, however, that section 841, under which Dr. Rosenberg was convicted, contains no provision to the effect that a violation of the Attorney General's regulations constitutes a criminal act.

illustrated by Dr. Rosenberg's activities. But we are sworn to uphold the law, and

> men are not subjected to criminal punishment because their conduct offends our . . . emotions or thwarts a general purpose sought to be effected by specific commands which they have not disobeyed. Nor are they to be held guilty of offenses which the statutes have omitted . . . to define and condemn. For the courts are without authority to repress evil save as the law has proscribed it and then only according to law.

Viereck v. United States, supra at 245.

I would REVERSE.

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APPENDIX B

Office of the Clerk
United States Court of Appeals for the Ninth Circuit
U. S. Court of Appeals and Post Office Building
7th & Mission Streets, P. O. Box 547
San Francisco, California 94101

MAR 31 1975

74-2197 - USA v. Maurice W. Rosenberg, M. D.

Dear Sir:

An opinion in the above case was filed today, and pursuant to Rule 36 of the Federal Rules of Appellate Procedure a judgment was entered affirming

MAR 31 1975

the judgment or order of the court below (or administrative agency).

Pursuant to Rule 41(a) the mandate of this court will issue 21 days after the entry of judgment, unless the court enters an order otherwise, or grants a stay of the mandate or a petition for rehearing is filed. If a petition for rehearing is filed and denied, the mandate shall issue 7 days after the entry of the order denying the petition.

[redacted]

Very truly yours,

[redacted], Clerk
U.S. Court of Appeals

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APPENDIX C

Title 21, United States Code

§ 801. Congressional findings and declarations

The Congress makes the following findings and declarations:

(1) Many of the drugs included within this subchapter have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people.

§ 802. Definitions

As used in this subchapter:

. . .

(2) The term "administer" refers to the direct application of a controlled substance to the body of a patient or research subject by—

(A) a practitioner (or, in his presence, by his authorized agent), or

(B) the patient or research subject at the direction and in the presence of the practitioner,

whether such application be by injection, inhalation, ingestion, or any other means.

. . .

(10) The term "dispense" means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary to prepare the substance for such delivery. The term "dispenser" means a practitioner who so delivers a controlled substance to an ultimate user or research subject.

(11) The term "distribute" means to deliver (other than by administering or dispensing) a controlled substance. The term "distributor" means a person who so delivers a controlled substance.

. . .

(20) The term "practitioner" means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

§ 822. Persons required to register—Annual registration

(a) Every person who manufactures, distributes, or dispenses any controlled substance or who proposes to engage in the manufacture, distribution, or dispensing of any controlled substance, shall obtain annually a registration issued by the Attorney General in accordance with the rules and regulations promulgated by him.

Authorized activities

(b) Persons registered by the Attorney General under this subchapter to manufacture, distribute, or dispense controlled substances are authorized to possess, manufacture, distribute, or dispense such substances (including any such activity in the conduct of research) to the extent authorized by their registration and in conformity with the other provisions of this subchapter.

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§ 829. Prescriptions—Schedule II substances

(a) Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed without the written prescription of a practitioner, except that in emergency situations, as prescribed by the Secretary by regulation after consultation with the Attorney General, such drug may be dispensed upon oral prescription in accordance with section 353(b) of this title. Prescriptions shall be retained in conformity with the requirements of section 827 of this title. No prescription for a controlled substance in schedule II may be refilled.

Schedule III and IV substances

(b) Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule III or IV, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed without a written or oral prescription in conformity with section 353(b) of this title. Such prescriptions may not be filled or refilled more than six months after the date thereof or be refilled more than five times after the date of the prescription unless renewed by the practitioner.

Schedule V substances

(c) No controlled substance in schedule V which is a drug may be distributed or dispensed other than for a medical purpose.

§ 841. Prohibited acts A—Unlawful acts

(a) Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally—

(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance; or

(2) to create, distribute, or dispense, or possess with intent to distribute or dispense, a counterfeit substance.

§ 842. Prohibited acts B—Unlawful acts

(a) It shall be unlawful for any person—

(1) who is subject to the requirements of part C to distribute or dispense a controlled substance in violation of section 829 of this title;

(2) who is a registrant to distribute or dispense a controlled substance not authorized by his registration to another registrant or other authorized person or to manufacture a controlled substance not authorized by his registration;

(3) who is a registrant to distribute a controlled substance in violation of section 825 of this title;

(4) to remove, alter, or obliterate a symbol or label required by section 825 of this title;

(5) to refuse or fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under this subchapter or subchapter II of this chapter;

(6) to refuse any entry into any premises or inspection authorized by this subchapter or subchapter II of this chapter;

(7) to remove, break, injure, or deface a seal placed upon controlled substances pursuant to section 824(f) or 881 of this title or to remove or dispose of substances so placed under seal; or

(8) to use, to his own advantage, or to reveal, other than to duly authorized officers or employees of the United States, or to the courts when relevant in any judicial proceeding under this subchapter or subchapter II of this chapter, any information acquired in the course of an inspection authorized by this subchapter concerning any method or process which as a trade secret is entitled to protection.

• • •

(c) (1) Except as provided in paragraph (2), any person who violates this section shall, with respect to any such violation, be subject to a civil penalty of not more than $25,000. The district courts of the United States (or, where there is no such court in the case of any territory or possession of the United States, then the court in such territory or possession having the jurisdiction of a district court of the United States in cases arising under the Constitution and laws of the United States) shall have jurisdiction in accordance with section 1355 of Title 28 to enforce this paragraph.

(2) (A) If a violation of this section is prosecuted by an information or indictment which alleges that the violation was committed knowingly and the trier of fact specifically finds that the violation was so committed, such person shall, except as otherwise provided in subparagraph (B) of this paragraph, be sentenced to imprisonment of not more than one year or a fine of not more than $25,000, or both.

§ 843. Prohibited acts C—Unlawful acts

(a) It shall be unlawful for any person knowingly or intentionally—

(1) who is a registrant to distribute a controlled substance classified in schedule I or II, in the course of his legitimate business, except pursuant to an order or an order form as required by section 828 of this title;

(2) to use in the course of the manufacture or distribution of a controlled substance a registration number which is fictitious, revoked, suspended, or issued to another person;

(3) to acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge;

(4) to furnish false or fraudulent material information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under this subchapter or subchapter II of this chapter; or

(5) to make, distribute, or possess any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit substance.